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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,536

01/12/2007

David Strand

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EXAMINER

SCHNEIDER, CRAIG M

ART UNIT

PAPER NUMBER

3753

MAIL DATE

DELIVERY MODE

09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,536	Applicant(s) STRAND ET AL.	
	Examiner CRAIG M. SCHNEIDER	Art Unit 3753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10, 12, 13, 15-17, 19, 21-24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, 12, 13, 15-17, 19, 21-24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/21/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/06 and 2/23/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The IDS dated 2/23/06 has been crossed through since the IDS is a duplicate of the IDS filed on 2/21/06.
2. The examiner added the publication date for the citation under the Non-Patent Literature section of 5/12/2005 for the IDS filed on 2/21/06.

Drawings

3. The drawings are objected to because the applicant is indicating that there are no figures associated with Figures 7-12, 23, and 24. The applicant should delete paragraphs 36 and 47 from the specification and renumber the drawings in sequential order. The specification would also need to be corrected to correspond with the corrected drawing numbers. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either

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“Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

The amendment to the specification dated 11/21/05 is supposed to replace the section entitled Priority Claim immediately after the Title of the Invention. It is not clear as to where this amendment should be placed because there is not a section after the Title of the Invention titled Priority Claim. Please clarify the placement of this amendment.

On page 12, para. 46, line 1 “FIG. 22” should be --FIG. 22A and 22B--.

On page 12, para. 48, line 1 “FIG. 25” should be --FIG 25A-25C--.

On page 14, para. 55, line 6 “upstream or first” should be --upstream of first--.

On page 16, para. 60, line 11 “entry port 2d. FIG. 1f” should be --exit port 2d.

FIG 1g--.

On page 16, para. 60, line 13 “FIG. 1g” should be --FIG. 1h--.

On page 25, para. 80, line 3 “member 16” should be --member 416--.

On page 35, para. 105, line 3 “second entry” should be --second exit--.

On page 35, para. 105, line 17 “port of the” should be --port or the--.

Appropriate correction is required.

Double Patenting

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5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-5, 7, 8, 10, 12, 13, 15-17, 19, 21, 23, 24, and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 30, 34, and 35 of copending Application No. 10/557,916. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim language in the pending application is broader than the claims of the copending application. That is, the more specific copending claims “anticipate” the broader application claims. See *in re Goodman* 29 USPQ2d 2010.

Regarding claim 8, the axial direction of the first chamber has not been defined per the claims; therefore the examiner is utilizing an axis through the first chamber that creates and obtuse angle with the first entry port.

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Regarding claim 12, the co-pending application does not claim that the first and second exit ports are positioned parallel to the axial direction of the first chamber.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first and second exit ports arranged in a parallel fashion to the axial direction of the first chamber, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japiske, 86 USPQ 70.

Regarding claims 16 and 17, the co-pending application does not claim that the charged analyte is eluting to the first or second exit port.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the electrodes of the copending application to elute the charged analyte to either of the exit ports, in order to provide the desired separation.

Regarding claim 19, the co-pending application fails to claim that the sample is introduced into the first chamber using an injector.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an injector to introduce the sample in to the first chamber, in order to introduce the sample into the first chamber.

Regarding claim 26, the co-pending application fails to claim that the sample further includes lipids, micelles, detergent or vesicles.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize various types of fluids including lipids, micelles, detergent or vesicles in the sample, since the separation of certain lipids, micelles, detergent or vesicles from the sample would provide a desired result with the device.

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. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 9 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 30 of copending Application No. 10/557,917 in view of Ivory et al. (6,277,258). The copending application fails to claim a separation media in the first chamber and that the media is selected from a group consisting of molecular sieves, ion-exchange media, and size exclusion media. Ivory et al. disclose the use of a separation media (16) selected from the group consisting of molecular sieves, ion-exchange media, and size exclusion media (col. 6, lines 18-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a separation media in the chamber of the bulk fluid flow gate of the copending application, in order to separate the electrodes from the process fluid.

Regarding claim 22, the co-pending application fails to claim that coolant is passed through the electrode housing. Ivory et al. disclose flowing a coolant into the electrode housing via conduits 215 and 217 (col. 8, lines 29-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a coolant to flow into the electrode housing as taught by Ivory et al. with the electrode housing of the co-pending application, in order to cool the electrodes.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-5, 7-10, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivory et al. (6,277,258).

Ivory et al. disclose a bulk fluid flow gate (100) comprising a first fluid flow chamber (112), and at least one electrode (22) operative when energized to generate an electric field in the first fluid flow chamber, wherein the first fluid flow chamber comprises a first fluid inlet port (320) configured to receive bulk fluid flow into the first fluid flow chamber, a first fluid outlet port (114) configured to pass bulk fluid from the first chamber, a second fluid inlet port (318) configured to receive sample fluid flow into the first fluid flow chamber at a location between the first fluid inlet port and the first fluid outlet port, and a second fluid outlet port (116) configured to pass fluid from the first fluid flow chamber, the first fluid outlet port and the second fluid outlet port being on opposite sides of the first fluid inlet port, and the bulk fluid flow gate when receiving a bulk fluid flow into the first fluid flow chamber via the first fluid inlet port and simultaneously a sample fluid flow into the first fluid flow chamber via the second inlet port, presenting greater hydrodynamic resistance to passing fluid from the first fluid flow chamber via the second outlet port than via the first fluid outlet port (col. 7, line 26 to col. 9, line 24).

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Note: the device as disclosed by Ivory et al. is capable of performing the functional language as claimed with the structure as disclosed and with the intended fluid. Further, the material that is worked upon by the device does not limit an apparatus claim if the apparatus is capable of working on the material (see MPEP 2115).

Regarding claim 3, the second fluid inlet port is configured to receive fluid flow into the first fluid flow chamber at a flow rate lower than the first fluid inlet port. The device of Ivory et al. is capable of having the fluid entering the second fluid inlet port at a flow rate lower than the first fluid inlet port.

Regarding claim 4, the at least one pair of electrodes is positioned proximate the first fluid flow chamber, being operative when energized to generate an electric field operative in the first fluid flow channel to move charged analyte received into the first fluid flow chamber via the second inlet port toward the second outlet port through a fluid flowing from the first inlet port to the first outlet port. The device of Ivory et al. is capable of performing the functional language.

Regarding claim 8, the first entry port is positioned at an obtuse angle to the axial direction of the first chamber. The axial direction of the first chamber has not been defined per the claims; therefore the examiner is utilizing an axis through the first chamber that creates an obtuse angle with the first entry port.

Regarding claim 9, the first chamber further comprises separation media (16) selected from the group consisting of molecular sieves, ion-exchange media, and size exclusion media (col. 6, lines 18-44).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivory et al. (6,277,258).

Ivory et al. disclose all the features of the claimed invention except that the gate has a microscale chamber.

It would have been an obvious matter of design choice to make the gate of Ivory et al. microscale, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Regarding claim 12, Ivory et al. disclose all the features of the claimed invention except that the first and second exit ports are positioned parallel to the axial direction of the first chamber.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first and second exit ports arranged in a parallel fashion to the axial direction of the first chamber, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japiske, 86 USPQ 70.

12. Claims 15-17, 19, 21-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivory et al. (6,277,258).

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Ivory et al. discloses a bulk fluid flow gate (100) comprising a at least one electrode (22) for generating an electric field, a first chamber (112) in communication with the at least one electrode, the first chamber comprising a first entry port (320), a first exit port (114), a second entry port (318) positioned between the first entry port and the first exit port, and a second exit port (116)(col. 7, line 26 to col. 9, line 24). Ivory et al further disclose that the bulk fluid flows in a counterflow direction of the sample fluid (col. 11, lines 43-50). Ivory et al. fails to disclose that a sample comprising at least one charged analyte that further includes lipids, micelles, detergent or vesicles is introduced into the first chamber through the second entry port and that a bulk fluid is introduced into the first chamber through the first entry port and that the bulk fluid flows substantially against the direction of migration of the at least one charged analyte in the electric field of the first chamber, the bulk fluid flowing with sufficient hydrodynamic force such that the hydrodynamic resistance at the first exit port is substantially greater than the hydrodynamic resistance at the second exit port.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize various types of fluids including a bulk fluid in the first entry port and a sample comprising at least one charged analyte in the second entry port of Ivory et al., since Ivory et al. disclose that the flow of "sample" flows in a counterflow of the bulk fluid (buffer) and the arrangement as presented above would be one viable arrangement that would accomplish the effect of the sample and bulk fluids flowing in a counterflow orientation.

Regarding claims 16 and 17, the apparatus as disclosed with the fluids entering into the entry ports would allow the charged analytes to elute through the first or second exit port depending on the electric field.

Regarding claim 19, in which the sample is introduced into the first chamber using an injector (col. 9, lines 25-36). A centrifugal pump or syringe pump would be considered an injector.

Regarding claim 21, the bulk fluid flow gate comprises an electrode housing (120) containing the at least one electrode.

Regarding claim 22, flowing a coolant into the electrode housing via conduits 215 and 217.

Regarding claim 23, the force of the electric field is disclosed as being adjustable (abstract) therefore with the bulk fluid entering the first entry port and the sample entering the second entry port the electric field that would be generated would exceed the hydrodynamic force generated by the bulk fluid flow so that the analyte migrates towards the second exit port.

Regarding claim 24, the electrode would apply an electric field gradient to the first chamber.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG M. SCHNEIDER whose telephone number is (571)272-3607. The examiner can normally be reached on M-F 8:00 -4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on (571) 272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Craig M Schneider/
Examiner, Art Unit 3753
August 31, 2009